

**Notice of Allowability**

Application No.

10/549,338

Examiner

Jason M. Nolan, Ph.D.

Applicant(s)

BELL ET AL.

Art Unit

1626

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/29/2005.
2. ☒ The allowed claim(s) is/are 1-15,24,25 and 27 (now 1-18).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 12/29/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### **DETAILED ACTION**

**Claims 1-15 & 24-28** are currently pending in the instant application. **Claims 16-23** are cancelled, **Claims 7 & 24** are amended, and **Claims 25-28** are new.

#### ***Priority***

This application is a 371 of PCT/US04/07289, filed on 3/10/2004.

Acknowledgement is made of Applicants' claim for benefit of US Provisional Patent Application 60/455,609, filed on 3/14/2003 and 60/486,642, filed 07/11/2003. Said claim has been made in the ADS and/or in the first paragraph of the Specification.

#### ***Information Disclosure Statement***

Applicants' information disclosure statement (IDS), filed on 12/29/2005 has been considered. Please refer to Applicants' copy of the 1449 submitted herein.

#### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Rubin on 12/12/2006.

The application has been amended as follows:

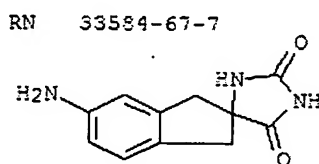
1. In **Claim 24**, delete the first chemical structure.
2. Cancel/Delete **Claims 26 & 28**.

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3. Delete the entire **Claim 27** and insert: - - A method of treating migraine headaches or cluster headaches, said method comprising the administration, to a person in need of such treatment, of a therapeutically effective amount of the compound of Claim 1. - -.

### ***Statement of Reasons for Allowance***

The present invention pertains to the compounds and compositions of formula I in **Claim 1** and methods of using these compositions for the treatment of migraine headaches or cluster headaches. The compounds according to formula I are free of the prior art; nothing known in the art anticipates or renders the compounds of the instant application obvious. There is no structurally similar prior art; however, the structural core was taught by Pinder *et al.* (*J. Med. Chem.* **1971**, *14*(9), 892-893) in compound RN 33584-67-7, shown below.

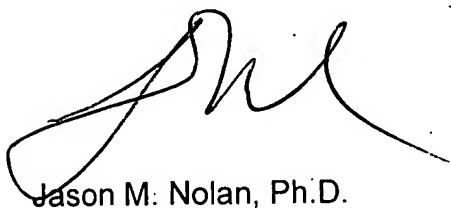


The known compound contains the bicyclic core including a spiro-connected heterocyclic ring; however, the compound does not have the amido-substituted nitrogen provided for in the instant application. One skilled in the art would be enabled to make and use the compounds taught herein using the teachings of the Specification in conjunction with the teachings in the prior art.

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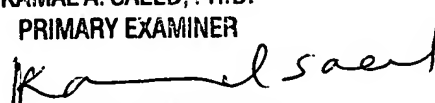
***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M<sup>c</sup>Kane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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KAMALA A. SAEED, PH.D.  
PRIMARY EXAMINER



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Date: December 13, 2006